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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,928	03/22/2007	Larry D. Ward	19746	7073

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EXAMINER	
KINSEY WHITE, NICOLE ERIN	
ART UNIT	PAPER NUMBER
1648	
MAIL DATE	DELIVERY MODE
09/08/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/575,928	WARD ET AL.	
	Examiner	Art Unit	
	NICOLE KINSEY WHITE	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 June 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,7-9,11 and 47-62* is/are pending in the application.

4a) Of the above claim(s) *47-62* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,7-9 and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Withdrawn Rejections

The rejection of claims 1-4, 12-15, 28-31 and 44-46 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been withdrawn in view of applicants' amendments to the claims, cancellation of claims 2 and 12-46, and applicants' arguments regarding the definition of "low retroviral load" in the specification.

The rejection of claims 44-46 under 35 U.S.C. §101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process has been withdrawn in view of applicants' cancellation of claims 44-46.

The rejection of claims 1-4, 12-15 and 28-31 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement has been withdrawn in view of applicants' amendments to the claims and the cancellation of claims 12-46.

The rejection of claims 1-4 and 12-15 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for reducing or delaying viral rebound during interruption of anti-retroviral drug treatment by administering a poxvirus vector encoding a retrovirus antigen and/or cytokine, does not reasonably provide enablement for preventing viral rebound during interruption of anti-retroviral drug treatment, or for reducing or delaying viral rebound by administering a poxvirus vector encoding a

homolog, analog, part or derivative of a retrovirus antigen and/or cytokine has been withdrawn in view of applicants' amendments to the claims.

The rejection of claims 1-4 are under 35 U.S.C. §102(b) as being anticipated by Ho *et al.* (WO 01/54701 A1) has been withdrawn in view of applicants' amendments to the claims.

The rejection of claims 12-15 and 28-31under 35 U.S.C. §103(a) as being unpatentable over Ho *et al.* (WO 01/54701) in view of Kent *et al.* (WO 00/28003) has been withdrawn in view of applicants' cancellation of claims 12-46.

The rejection of claims 1-4, 12-15, and 28-31 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 3 of U.S. Patent No. 7,276,242 B1 in view of Rosenwirth *et al.* (1999) has been withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, 4, 7-9 and 11 are rejected under 35 U.S.C. §103(a) as being unpatentable over Ho *et al.* (WO 01/54701) in view of Kent *et al.* (WO 00/28003, cited in IDS filed 26 October 2006).

The instant claims are directed to a method comprising administering to a subject a poxvirus vector encoding an HIV antigen and IFN-γ, in conjunction with interrupted anti-retroviral drug therapy.

Ho *et al.* teaches a method of permitting cessation of antiviral therapy on HIV-infected subjects, who have a viral load of less than 5,000 viral copies per ml of plasma (limitation in claims 3 and 4) and a $CD4^+$ T-cell count of above 500 cells/ml, and who have been treated with a potent combination of antiviral agents that contributed to a lower viral copy number and equal or higher $CD4^+$ T-cell count than before treatment, without virus rebound or with at least a delayed virus rebound or a decreased post-rebound viral load, by inducing both humoral and cell-mediated immunity and achieving an immunological control of persistent infectious virus after discontinuation of antiviral therapy (page 2, lines 15-34). The method comprises inducing HIV-specific (limitation in claim 2) immune responses by administering an attenuated recombinant poxvirus (e.g., avipox, vaccinia virus, or recombinants thereof) that includes [one] or more nucleic acids encoding one or more HIV-specific immunogens (page 3, lines 2-5 and page 9, lines 12-22).

Although Ho *et al.* specifically suggests combining an HIV antigen with an immunostimulatory or co-stimulatory molecules such as interleukin 2, which is a cytokine (page 3, lines 6-9), Ho *et al.* does not disclose co-expressing IFN-γ with an HIV antigen in the poxvirus vector.

Kent *et al.* discloses an immunogenic construct comprising an avipox virus vector encoding HIV-1 Gag and/or Pol or derivatives thereof and interferon-gamma (IFN-γ) or

a functional derivative thereof that is effective in inducing, enhancing or otherwise stimulating an immune response to HIV Gag and/or Pol. See page 3, lines 15-31.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Ho *et al.* so as to replace the poxvirus vector with the avipox vector encoding HIV-1 Gag and/or Pol or derivatives thereof and IFN-γ or a functional derivative thereof as taught by Kent *et al.* or to include IFN-γ in the vector of Ho et al. One having ordinary skill in the art would have been motivated to make such a modification to enhance the HIV-specific immune responses by additionally expressing IFN-γ as taught by Kent *et al.* (see, for example, page 28, lines 4-14). There would have been a reasonable expectation of success, given the effectiveness of the avipox vector encoding HIV-1 Gag and/or Pol and IFN-γ in inducing, enhancing or otherwise stimulating an immune response to HIV Gag and/or Pol, as taught by Kent *et al.*

Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

No claim is allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICOLE KINSEY WHITE whose telephone number is (571)272-9943. The examiner can normally be reached on Monday through Friday from 9:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Zacharia Lucas can be reached on (571) 272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicole Kinsey White/
Examiner, Art Unit 1648

/Stacy B Chen/
Primary Examiner, Art Unit 1648